UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

ANGELA COLEMAN, Plaintiff, v. ZIMMER, INC.; ZIMMER HOLDINGS, INC.; AND ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS, INC., Defendants.	Case No. **COMPLAINT AND JURY TRIAL DEMAND**

NOW COMES the Plaintiff, Angela Coleman, by and through her undersigned Counsel, and for her Complaint against the Defendants, alleges as follows:

NATURE OF THE CASE

1. This is an action for damages suffered by Angela Coleman, as a direct and proximate result of Defendants' wrongful conduct in connection with the development, design, manufacture, distribution, and selling of Defendants' knee replacement product, the Zimmer NexGen total knee replacement system, including the Zimmer NexGen LPS-Flex Gender Solutions femoral component (hereinafter "Zimmer NexGen Knee")

2. Defendants knew or should have known that the Zimmer NexGen Knee can loosen in patients, such as Plaintiff, causing personal injury, significant pain, and loss of movement, and that this injury can only be remedied through subsequent revision surgery and/or knee replacement. Further, Defendants misled health care professionals and the public into believing that the Zimmer NexGen Knee was safe and effective for use in

knee replacement surgery; engaged in deceptive, misleading and unconscionable promotional or sales methods to convince health care professionals to utilize the Zimmer NexGen Knee, even though Defendants knew or should have known that the Zimmer NexGen Knee was unreasonably unsafe; and failed to warn health care professionals and the public about the safety risks of the Zimmer NexGen Knee.

PARTIES

3. Plaintiff Angela Coleman is a citizen of the State of Michigan, and a resident of Flint, Michigan

4. Defendant Zimmer, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business located in Warsaw, Indiana.

5. Defendant Zimmer Holdings, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business located in Warsaw, Indiana.

6. Defendant Zimmer Orthopaedic Surgical Products, Inc. is a corporation organized and existing under the laws of Ohio, and has its principal place of business in Dover, Ohio.

7. At all times material hereto, Defendants developed, designed, tested, manufactured, distributed, marketed, and sold the Zimmer NexGen Knee. Defendants' products, including the Zimmer NexGen Knee, are sold throughout the world, including within the State of Michigan.

JURISDICTION AND VENUE

8. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds $75,000 exclusive of interest and costs.

9. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. § 1391(a), as a substantial number of the events, actions or omissions giving rise to Plaintiff's claims occurred in this district. At all times material hereto, Defendants conducted substantial business in this district.

FACTUAL BACKGROUND
KNEE REPLACEMENT BACKGROUND

10. Total Knee Arthroplasty ("TKA"), also called total knee replacement, is a common medical procedure performed. The surgery is designed to help relieve pain and improve joint function in people with severe knee degeneration due to arthritis or trauma.

11. Upon information and belief, the TKA procedure is done by separating the muscles and ligaments around the knee to expose the inside of the joint. The ends of the thigh bone (femur) and the shin bone (tibia) are removed as is often the underside of the kneecap (patella).

12. Upon information and belief, about 85 to 90 percent of total knee replacements are successful for up to ten years.

13. *Mechanical loosening* means that for some reason (other than infection) the attachment between the artificial knee and the bone has become loose.

14. Loosening can occur with any component of the artificial knee: the femoral, the tibial or the patellar component.

15. Upon information and belief, loosening of an artificial knee can be diagnosed using X-ray images that show one or more radiolucent lines around the contours of the artificial knee joint.

16. A loose artificial knee is a problem because it causes pain and wearing away of the bone. A painful loose knee can restrict the patient's daily activities severely. A loose artificial knee also involves severe psychical burden for the patient.

17. Once the pain becomes unbearable or the individual loses function of the knee, another operation may be required to revise the knee replacement. A loose, painful artificial knee can usually, but not always, be replaced.

18. The purpose of knee revision surgery is to remove a failed knee implant and replace it with a new one.

19. Upon information and belief, a revision operation of a failed knee implant is problematic because the surgeon must reconstruct the severe bone loss caused by bone destruction around the failed total knee prosthesis, and restore the stability in the revised total knee.

20. Upon information and belief, the results of a revision operation are not as good as the first, and the risks of complications are higher. The range of motion in the knee after revision surgery may be reduced and the ability to ambulate may also be diminished. The rate of loosening increases after revision surgery.

ZIMMER NEXGEN KNEE FACTS

21. Zimmer was founded in 1927, and purports to be a worldwide leader in the design and manufacture of orthopaedic reconstructive, spinal and trauma devices, dental implants, and related orthopaedic surgical products.

22. The Zimmer NexGen Knee uses a "high-flex" femoral component that purports to allow a greater degree of flexion than the standard femoral component.

23. The Defendants generally, manufactured, labeled, packaged, distributed, supplied, marketed, advertised, and/or otherwise engaged in all activities that are part and parcel of the sale and distribution of a pharmaceutical, and by said activities, caused the Zimmer NexGen Knee to be placed into the stream of commerce throughout the United States.

24. Defendants made, participated in and/or contributed to filings with the FDA in conjunction with the approval process for the Zimmer NexGen Knee.

25. Upon information and belief, Defendants were in control of the design, assembly, manufacture, marketing, distribution, packaging, labeling, processing, supplying, promotion, sales, and the issuance of product warnings and related information with respect to the Zimmer NexGen Knee.

26. Defendants were at all times material hereto subject to the laws of the United States of America, including provisions relating to the FDA, and the rules and regulations thereof, in conjunction with the approval process, labeling, and other after-market activities that pertain to the Zimmer NexGen Knee.

27. The Zimmer NexGen Knee has been widely advertised, marketed and represented by the Defendants as a safe and effective treatment.

ZIMMER NEXGEN KNEE PROBLEMS

28. Studies show that a knee implant that allows for higher flexation, like the Zimmer NexGen Knee, is more likely to fail because higher flexation places the knee implant at a higher risk of loosening.

29. Additionally, The Journal of Bone and Joint Surgery (British Edition) published a peer reviewed study by professors at the Seoul National University College of Medicine in 2007 titled, *High Incidence of Loosening of the Femoral Component in the Legacy Posterior Stabilized-Flex Total Knee Replacement* reporting that 38% of the implanted LPS high-flex knees were loose shortly after 2 years post implant. From the group of patients with loose knees, over half (56%) had their knee revised due to pain.

30. On or about September 15, 2010, Defendants sent an "Urgent Device Correction and Removal" notice to surgeons regarding certain LPS high-flex femoral components.

31. On or about December 2, 2010, the FDA issued a Class II Recall for certain LPS high-flex femoral components because the component exhibited a nonconforming internal CAM radius. Plaintiff's Zimmer NexGen Knee was one of the systems subject to the recall.

32. From the time that Defendants first began selling the Zimmer NexGen Knee in the United States, the product labeling and product information for the Zimmer NexGen Knee failed to contain adequate information, instructions, and warnings

concerning implantation of the product and the increased risks that the Zimmer NexGen Knee can loosen in patients.

33. Despite its knowledge of the serious injuries associated with using the Zimmer NexGen Knee, Defendants engaged in a marketing and advertising program which as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that using the Zimmer NexGen Knee was safe.

34. Upon information and belief, Defendants downplayed and understated the health hazards and risks associated with the use of the Zimmer NexGen Knee and through promotional literature as well as sales visits to orthopaedic surgeons, deceived doctors and potential users of the Zimmer NexGen Knee by relaying positive information, while concealing the nature and extent of known adverse and serious health effects.

FACTUAL ALLEGATIONS

35. On August 3, 2007, Plaintiff's physician implanted a Zimmer NexGen Knee system into Plaintiff.

36. Prior to August 3, 2007, the treating physician for Plaintiff, as well as Plaintiff, was exposed to the aforementioned advertising and marketing campaign directed by the Defendants.

37. Plaintiff and Plaintiff's physician, either through direct promotional contact with Defendants' sales force, through word-of-mouth from other health care providers, and/or through promotional materials, received the information the Defendants intended

that they receive, to-wit: that the Zimmer NexGen Knee was safe and effective for use in TKA procedures.

38. Plaintiff began experiencing severe and debilitating pain after implant.

39. Plaintiff returned to Plaintiff's physician several times due to consistent pain in her knee.

40. On August 21, 2008, Plaintiff had a second surgery to revise/replace her previously implanted Zimmer NexGen Knee because of loosening. Plaintiff's entire artificial knee system was replaced. Plaintiff was never told, by any source, that her knee failed because the product itself was defectively designed.

41. As a direct and proximate result of the use of the Zimmer NexGen Knee, Plaintiff suffered, and continues to suffer, serious bodily injury and harm.

42. As a direct and proximate result of the use of the Zimmer NexGen Knee, Plaintiff incurred, and continues to incur, medical expenses to treat her injuries and condition.

43. At no time material to her use of the Zimmer NexGen Knee was Plaintiff or her physicians told, warned, or given information about the higher risks of loosening in the Zimmer NexGen Knee.

COUNT I
STRICT LIABILITY

44. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

45. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of the Zimmer NexGen Knee. Defendants designed, manufactured, marketed, and sold the Zimmer NexGen Knee to medical professionals and their patients, knowing it would be implanted for knee replacements.

46. Zimmer NexGen Knee as designed, manufactured, marketed and sold by Defendants reached Plaintiff without substantial change in its condition and was used by Plaintiff in a reasonably foreseeable and intended manner.

47. Zimmer NexGen Knee was "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff. The Zimmer NexGen Knee was dangerous to an extent beyond that which would be contemplated by the ordinary consumer and the benefits of the design outweighed the risk of danger inherent in the design.

48. The Zimmer NexGen Knee was used in the manner for which it was intended, that is, for artificial knee replacement. This use resulted in injury to Plaintiff.

49. At no time did Plaintiff have reason to believe that Zimmer NexGen Knee was in a condition not suitable for its proper and intended use among patients.

50. Plaintiff was not able to discover, nor could she have discovered through theexercise of reasonable care, the defective design and/or manufacture of the Zimmer NexGen Knee. Further, in no way could Plaintiff have known that Defendants had designed, developed, and manufactured the Zimmer NexGen Knee in such a way as to increase the risk of harm or injury to the recipients of it.

51. The Zimmer NexGen Knee is defective in design and/or manufacture because of its propensity to loosen and cause patients unnecessary pain and repeat surgical procedures.

52. The Zimmer NexGen Knee is unreasonably dangerous because it was sold to Plaintiff without adequate warnings regarding, *inter alia*, the propensity of Zimmer NexGen Knee to loosen and cause serious pain and necessitate additional surgery; the post-marketing experience of higher rates of loosening and revision surgery with the Zimmer NexGen Knee; and the probability of suffering loosening and revision surgery.

53. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable at the time Defendants sold the Zimmer NexGen Knee to Plaintiff.

54. Defendants knew or should have known of the defective and dangerous nature of the Zimmer NexGen Knee. Despite this knowledge and information, Defendants failed to adequately and sufficiently warn Plaintiff and her physicians that Zimmer NexGen Knee causes serious injuries including, loosening and revision surgery.

55. As a direct and proximate result of Defendants' wrongful conduct, including the Zimmer NexGen Knee's defective and dangerous design, manufacture and/or inadequate warnings, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT II
PRODUCTS LIABILITY – FAILURE TO WARN

56. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

57. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Zimmer NexGen Knee and, in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Zimmer NexGen Knee.

58. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and her prescribing physician, of the true risks of the Zimmer NexGen Knee, including that the Zimmer NexGen Knee could loosen, causing severe pain and injury, and requiring further treatment, including revision surgery and/or knee replacement.

59. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Zimmer NexGen Knee. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician, would have prescribed the Zimmer NexGen Knee, or no consumer, including Plaintiff, would have purchased and/or used the Zimmer NexGen Knee.

60. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Zimmer NexGen Knee. Had they

done so, healthcare professionals, including Plaintiff's physician, could have safely and effectively implanted the Zimmer NexGen Knee, without causing serious pain and injury to patients, including Plaintiff.

61. The Zimmer NexGen Knee, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendants knew or should have known that there was reasonable evidence of an association between the Zimmer NexGen Knee and knee replacement loosening causing serious injury and pain. Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote the Zimmer NexGen Knee.

62. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

63. As a direct and proximate result of Defendant's conduct as aforesaid, Plaintiff suffered serious and permanent non-economic and economic injuries.

COUNT III
PRODUCTS LIABILITY – DESIGN DEFECT

64. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

65. Defendants researched, developed, manufactured, distributed, marketed, promoted, supplied and sold the Zimmer NexGen Knee, which is defective and unreasonably dangerous to consumers.

66. The Zimmer NexGen Knee is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. The Zimmer NexGen Knee is defective in design or formulation in that it lacks efficacy and/or it poses a greater likelihood of injury than other knee replacement devices and similar knee replacement devices on the market and is more dangerous than ordinary consumers can reasonably foresee.

67. If the design defect were known at the time of manufacture, a reasonable person would have concluded that the utility of the Zimmer NexGen Knee did not outweigh the risk of marketing a product designed in that manner.

68. The defective condition of the Zimmer NexGen Knee rendered it unreasonably dangerous and/or not reasonably safe, and the Zimmer NexGen Knee was in this defective condition at the time it left the hands of the Defendants. The Zimmer NexGen Knee was expected to and did reach consumers, including Plaintiff, without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

69. Plaintiff and her physician were unaware of the significant hazards and defects in the Zimmer NexGen Knee.

70. The Zimmer NexGen Knee was unreasonably dangerous and/or not reasonably safe in that it was more dangerous than would be reasonably contemplated by the ordinary user. During the period that Plaintiff used the Zimmer NexGen Knee, it was being utilized in a manner that was intended by Defendants.

71. At the time Plaintiff received and used the Zimmer NexGen Knee, it was represented to be safe and free from latent defects.

72. Defendants are strictly liable to Plaintiff for designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable uses at the time it left the control of Defendants because of the design defects.

73. Defendants knew or should have known of the danger associated with the use of the Zimmer NexGen Knee, as well as the defective nature of the Zimmer NexGen Knee, but continued to design, manufacture, sell, distribute, market, promote and/or supply the Zimmer NexGen Knee so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the Zimmer NexGen Knee.

74. As a direct and proximate cause of the design defect and Defendants' misconduct as set forth herein, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries.

75. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV
NEGLIGENCE

76. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

77. At all relevant times, Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of Zimmer NexGen Knee, including a duty to ensure that the Zimmer NexGen Knee did not pose a significantly increased risk of bodily injury to its users.

78. Defendants had a duty to exercise reasonable care in the advertising and sale of Zimmer NexGen Knee, including a duty to warn Plaintiff and other consumers, of the dangers associated with the consumption of the Zimmer NexGen Knee that were known or should have been known to Defendants at the time of the sale of the Zimmer NexGen Knee to the Plaintiff.

79. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of the Zimmer NexGen Knee because Defendants knew or should have known that the Zimmer NexGen Knee had a propensity to cause serious injury, including loosening and revision surgery

80. Defendants failed to exercise ordinary care in the labeling of the Zimmer NexGen Knee and failed to issue adequate pre-marketing or post-marketing warnings to prescribing doctors and the general public regarding the risk of serious injury, including, loosening and revision surgery.

81. Defendants knew or should have known that Plaintiff could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

82. Defendants breached their duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances.

83. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of the Zimmer NexGen Knee, Plaintiff was implanted with the Zimmer NexGen Knee and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT V
BREACH OF EXPRESS WARRANTY

84. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

85. Defendants advertised, labeled, marketed and promoted its product, the Zimmer NexGen Knee, representing the quality to health care professionals, the FDA, Plaintiff, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Zimmer NexGen Knee would conform to the representations. More specifically, Defendants represented that the Zimmer NexGen Knee was safe and

effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective to treat Plaintiff's condition.

86. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

87. The Zimmer NexGen Knee did not conform to the representations made by Defendants in that the Zimmer NexGen Knee was not safe and effective, was not safe and effective for use by individuals such as Plaintiff, and/or was not safe and effective to treat in individuals, such as Plaintiff.

88. At all relevant times, Plaintiff used the Zimmer NexGen Knee for the purpose and in the manner intended by Defendants.

89. Plaintiff and Plaintiff's physician, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

90. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

91. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer NexGen Knee, Plaintiff was implanted with Zimmer NexGen Knee and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for

which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT VI
BREACH OF IMPLIED WARRANTIES

92. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

93. The Zimmer NexGen Knee was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor was the Zimmer NexGen Knee minimally safe for its expected purpose.

94. At all relevant times, Plaintiff used the Zimmer NexGen Knee for the purpose and in the manner intended by Defendants.

95. Plaintiff and Plaintiff's physician, by the use of reasonable care could not have discovered the breached warranty and realized its danger.

96. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

97. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer NexGen Knee, Plaintiff was implanted with Zimmer NexGen Knee and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for

which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiff prays for relief against Defendants, jointly and severally, as follows:

1. Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all her injuries and damages, both past and present;

2. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of her injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent instability and loss of balance, and pain and suffering.

3. Double or triple damages as allowed by law;

4. Attorneys' fees, expenses, and costs of this action;

5. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

6. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

April 29, 2011

Respectfully submitted,

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